REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims **1-5, 17-19, 21-32, 41, 42, 44-47, 67** and **68** are pending.

Claims **1-3, 17-19, 21-31, 41, 42** and **44-47** have been rejected.

Claims **67** and **68** have been allowed.

Claims **4, 5** and **32** have been objected to.

Claims **1** and **29** have been amended in this submission. Applicants respectfully assert that the amendments to the claims add no new matter.

Allowable Subject Matter

In the Office Action, the Examiner stated that claims 4-5 and 32 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants are grateful for the indication of allowability, but respectfully decline to amend the claims as suggested by the Examiner at this time. It is respectfully submitted that all claims are allowable at least for the reasons set forth below.

Support for Amendments

Claims 1 and 29 have been amended to recite that the detachment is "without endoscopic intervention. This amendment has sufficient support throughout the specification. The abstract states that the "intra-luminal medical device includes a fixation mechanism to attach the medical device to tissue within a body lumen, and a detachment mechanism to permit selective detachment of the medical device from the tissue attachment site without the need for endoscopic or surgical intervention." Paragraph [0012] of the application as published states that "[w]hen embodied in a device for intra-luminal monitoring or stimulation, for example, the invention includes a variety of features that facilitate the controlled detachment of such a device without the need for endoscopic or surgical intervention."

Accordingly, it is respectfully submitted that the amendments to the claims add no new matter and are fully supported in the application as filed.

CLAIM REJECTIONS

35 U.S.C. § 102 Rejections

In the Office Action, the Examiner rejected claims 1-3, 17, 18, 24-31, 41 and 45-47 under 35 U.S.C. § 102(e), as being anticipated by Cartledge et al. (US Patent No. 7,175,660). In addition to the extensive discussions in previous submissions regarding the Cartledge reference, which need not be repeated herein, Applicants respectfully traverse the rejection for at least the following reasons.

The Cartledge reference discloses:

> A system for implanting a surgical device to control the circumference of internal anatomic passages corrects physiologic dysfunctions resulting from a structural lumen which is either too large or too small. Implants are disclosed which employ various means for adjusting and maintaining the size of an orifice to which they are attached. Systems permit the implants to be implanted using minimally invasive procedures and permit final adjustments to the circumference of the implants after the resumption of normal flow of anatomic fluids in situ. Methods are disclosed for using the implants to treat heart valve

> abnormalities, gastroesophageal abnormalities, anal incontinence, and the like. (Abstract, emphasis added)

With respect to the adjustment means in particular, the Examiner has cited the following portion of the Cartledge reference:

> In yet other embodiments according to the present invention, the adjustment means may comprise a snare or purse string-like mechanism in which a suture, a band, a wire or other fiber structure, braided or non-braided, monofilament or multifilament, is capable of affecting the anatomic and/or physiologic effects of the implant device on a native anatomic recipient site upon varying tension or motion imparted to said wire or fiber structure by a surgeon or other operator. Such an adjustment means may be provided as a circular or non-circular structure in various embodiments. Changes in tension or motion may change the size and/or shape of the implant. (col. 15, lines 47-57, emphasis added).

It is clear from the disclosure of the Cartledge reference that such tension or motion imparted to the wire or fiber structure is performed by surgical or endoscopic intervention (although perhaps minimal). For example, Fig. 23 clearly shows such surgical or endoscopic intervention in order to adjust the device:

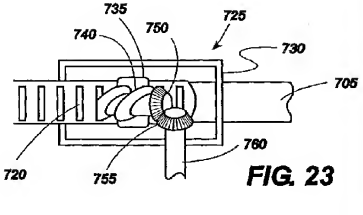

FIG. 23

The accompanying portion of the specification clearly explains the surgical or endoscopic intervention required to adjust the device:

> . . . The implant body 705 is also provided with an adjustable section 715, which is provided in this example with a series of adjustment stops 720. . . In the embodiment shown in FIGS. 21 24, the adjustment stops 720 are engaged by a geared connector 725. . . FIG. 23 shows details of an exemplary geared connector 725, in which a housing 730

> is connected to the implant body 705. The housing 730 contains and supports a mechanical worm 740 with an attached first geared head 750 which mates with a second geared head 755. The second geared head 755 is attached to an adjustment stem 760 which is machined to receive a screwdriver-like adjustment element. . . In the present example, the adjustment element is provided as a finely coiled wire with a distal tip machined to be received by a receiving slot in the adjustment stem 760 (not shown). The relationship between the distal tip of the adjustment element and the adjustment stem 760 is mechanically similar to a screwdriver bit and screwhead, such that torsion imparted to the adjustment means by the operator will result in the turning of the adjustment stem 760 and second geared head 755 allows motion of the first geared head 750 and worm 740, which creates motion of the adjustable implant section 715 as the worm engages with the series of adjustment tops 725. . . (col. 11 line 59 – col. 12 line 39, emphasis added)

Accordingly, it is clear that the Cartledge reference does not teach, disclose or otherwise render obvious "a controlled detachment mechanism mechanically actuating the fixation mechanism to selectively detach the device housing from the surface of the body lumen without endoscopic intervention" as recited in claim 1, or "activating the fixation mechanism with a controlled mechanically actuated detachment mechanism carried by the medical device to detach the medical device from the surface of the body lumen without endoscopic intervention, wherein the detachment mechanism is activated in response to receipt of a control signal from a controller external to the body lumen," as recited in claim 29.

Therefore, for at least this reason, claims 1 and 29 are allowable over the Cartledge reference, as are claims 2, 3, 17, 18, 24-28, 30, 31, 41 and 45-47, which depend therefrom.

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 3 and 31 under 35 U.S.C. § 103(a), as being unpatentable over Cartledge et al. (US Patent No. 7,175,660) in view of Kilcoyne et al. (US Patent No. 6,689,056).

The Kilcoyne reference discloses "an ambulatory system for monitoring one or more physiological parameters in a body lumen, such as the esophagus. The system includes an

implantable probe having a sensor for the physiological parameter and a transmitter for transmitting data to an external receiver. The probe may be used for monitoring any of various physiological parameters, including pH, temperature, and pressure, within the esophagus or other body lumens. Methods and deployment catheters are also disclosed." (Abstract)

Preliminary, it would not have been obvious to combine the teachings of the Cartledge reference with those of the Kilcoyne reference. The implantable device disclosed by the Cartledge reference is not designed to pass through the gastrointestinal tract and be excreted naturally. Rather, as is clear from the shape and width of the ring, as well as from the sharp barbs, if the device is not removed endoscopically or surgically, it will lodge inside the body and injure the patient. Therefore, in this respect, it is the antithesis of the Kilcoyne reference, which discloses a naturally excreted device.

In any event, the Kilcoyne reference does not teach, disclose or otherwise render obvious "a controlled detachment mechanism mechanically actuating the fixation mechanism to selectively detach the device housing from the surface of the body lumen without endoscopic intervention" as recited in claim 1, or "activating the fixation mechanism with a controlled mechanically actuated detachment mechanism carried by the medical device to detach the medical device from the surface of the body lumen without endoscopic intervention, wherein the detachment mechanism is activated in response to receipt of a control signal from a controller external to the body lumen," as recited in claim 29.

Accordingly, claims 3 and 31, which incorporate the elements of claims 1 and 29, respectively, are allowable over the Cartledge and Kilcoyne references.

In the Office Action, the Examiner rejected claims 19, 22-23 and 42 under 35 U.S.C. § 103(a), as being unpatentable over Cartledge et al. (US Patent No. 7,175,660) in view of Imran et al. (US Patent No. 6,535,764).

The Imran reference discloses:

> A device, system and method for diagnosing and treating gastric disorders. . . A functional device resides within the patient's stomach and is secured to the stomach wall by an attachment device. . . An

> endoscopic delivery system delivers the functional device through the esophagus and into the stomach where it is attached the stomach wall. The endoscopic instruments attach or remove the attachment devices and functional devices from the stomach and may be used to assist in determining the optimal attachment location. (Abstract, emphasis added)

Therefore, the Imran reference does not teach, disclose or otherwise render obvious "a controlled detachment mechanism mechanically actuating the fixation mechanism to selectively detach the device housing from the surface of the body lumen without endoscopic intervention" as recited in claim 1, or "activating the fixation mechanism with a controlled mechanically actuated detachment mechanism carried by the medical device to detach the medical device from the surface of the body lumen without endoscopic intervention, wherein the detachment mechanism is activated in response to receipt of a control signal from a controller external to the body lumen," as recited in claim 29.

Accordingly, claims 19, 22-23 and 42, which incorporate the elements of claims 1 and 29, respectively, are allowable over the Cartledge and Imran references.

In view of the foregoing amendments and remarks, Applicants assert that the pending claims are allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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